MAR 2 9 2001

510(k) Summary

K010588

Introduction

According to the requirements established in the Food and Drug Administration's guidance document entitled "The New 510(k) Paradigm: Alternate Approaches to Demonstrating Substantial Equivalence in Premarket Notifications", the following information provides sufficient detail to understand the basis for a determination of substantial equivalence.

1) Submitter name, address, contact

Roche Diagnostics Corporation
9115 Hague Rd.
Indianapolis, IN 46250
(317) 576-3544

Contact Person: Kay A. Taylor

Date Prepared: February 26, 2001

2) Device name

Proprietary name: Elecsys CA 15-3 II Assay
Common name: CA 15-3 Test System
Classification name: System Test, Tumor Marker, Monitoring, Breast

3) Predicate device

We claim substantial equivalence to the currently marketed Elecsys CA 15-3 Assay (K001468).

510(k) Summary, Continued

4) Device Description

The Elecsys CA 15-3 II Test System is a two step sandwich immunoassay with streptavidin microparticles and electrochemiluminescence detection.

Results are determined using a calibration curve that is generated specifically on each instrument by a 2-point calibration and a master curve provided with the reagent bar code.

5) Intended use

For the quantitative determination of CA 15-3 in human serum and plasma.

6.) Substantial equivalence

The table below indicates the similarities between the modified Elecsys CA 15-3 II and the predicate, Elecsys CA 15-3 (K001468). In summary, the Elecsys CA 15-3 II described in this submission is, in our opinion, substantially equivalent to the predicate device.

Comparison of Proposed and Predicate Device

Topic	Modified Elecsys CA 15-3 II	Elecsys CA 15-3 (cleared K001468)
Intended Use	Same	For the quantitative determination of CA 15-3 in human serum and plasma.
Indication for Use	Same	To aid in the management of breast cancer patients. In conjunction with other clinical and diagnostic procedures, serial testing with the CA 15-3 assay is an aid in the early detection of recurrence in previously treated Stage II and III breast cancer patients. For monitoring response to therapy in metasitic breast cancer patients.
Sample Type	Same	Human serum and plasma
Analytical Specificity	Same	Based on monoclonal 115D8 and DF3 antibodies available from Centocor.
Measuring Range	Same	1.0 – 300 U/mL

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAR 2 9 2001

Ms. Kay A. Taylor
Regulatory Affairs, Laboratory Systems
Roche Diagnostics Corporation
9115 Hague Road
P.O. Box 50457
Indianapolis, Indiana 46250-0457

Re: K010588
Trade Name: Roche Diagnostics Elecsys CA 15-3 II Assay
Regulatory Class: II
Product Code: MOI
Dated: February 26, 2001
Received: February 27, 2001

Dear Ms. Taylor:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K 010588
Device Name: **Elecsys CA 15-3 II Assay**

Indications for Use:

Immunological in vitro assay for the quantitative determination of CA 15-3 in human serum and plasma to aid in the management of breast cancer patients. In conjunction with other clinical and diagnostic procedures, serial testing with the CA 15-3 assay is an aid in

- Early detection of recurrence in previously treated Stage II and III breast cancer patients.
- Monitoring response to therapy in metasitic breast cancer patients.

The electrochemiluminescence immunoassay "ECLIA" is intended for use on the Roche Elecsys 1010 and 2010 immunoassay analyzers.

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number 3/30/01

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

(Optional Format 1-2-96)